

REMARKS

Reconsideration of this application in view of the above amendments and following remarks is requested. After entry of this reply, claims 22-27, 29-35 and 66-101 are pending in the application. In this Response and Amendment, claims 22, 27, 29, 32 and 35 are amended, claims 28 and 42-65 are canceled (claims 1-21 and 36-41 were previously canceled), and claims 66-101 are added.

Notice of Prior and Ongoing Litigation Involving Related Patent US 6,881,211

A Patent related to the present application, US 6,881,211 (the '211 Patent), is and has been involved in the following litigations:

- (A) Medical Components, Inc. vs. Arrow International, Inc., Civil Action No. 07-2852 (E.D. Pa., filed July 11, 2007; and
- (B) Medical Components, Inc. vs. Spire Biomedical, Inc., Civil Action No. 07-2853 (E.D. Pa., filed July 11, 2007; closed February 21, 2008.

The '211 Patent is a division of US 6,719,749 (the '749 Patent), the '749 Patent being a parent to the present application. Applicant wishes to advise the Examiner that Applicant is in the process of preparing an Information Disclosure Statement (IDS) in compliance with MPEP §2001.06(c), to disclose, inter alia, pleadings, discovery and other litigation materials, and will be filing the IDS in the near future.

Decision on Petition under 37 CFR § 1.137(b) issued December 27, 2007

As a further preliminary matter, Applicant's undersigned representative addresses issues noted in the Decision on Petition under 37 CFR § 1.137(b), issued December 27, 2007. In the Decision on Petition, granting revival of the present application, Petitions Examiner Hicks states that it is not apparent whether the person signing the statement of unintentional delay was in a

position to have firsthand or direct knowledge of the facts and circumstances of the delay at issue. Petitions Examiner Hicks treats the Petition as having been made as a result of reasonable inquiry into the facts and circumstances of such delay, but states that, in the event such an inquiry has not been made, Petitioner must make such an inquiry, and upon any discovery that the entire delay was not unintentional, Petitioner must notify the Office.

Petitioner (Applicant's undersigned representative) hereby confirms that reasonable inquiry into the facts and circumstances of the unintentional delay was made prior to the filing, on June 26, 2007, of Applicant's Petition for Revival under 37 CFR § 1.137(b).

Further, Petitions Examiner Hicks states that there is no indication that the person signing the Petition was ever given power of attorney to prosecute the application, and if the person signing the Petition desires to receive future correspondence regarding the application, the appropriate power of attorney document must be submitted.

Petitioner (Applicant's undersigned representative) was appropriately given power of attorney to prosecute the application by the Assignee(s), such power being duly and subsequently submitted to the Office. Accordingly, all correspondence is currently being received by Petitioner. Applicant's undersigned representative thanks Petitions Examiner Hicks for the notification.

NonFinal Office Action dated February 15, 2008

In the Office Action dated February 15, 2008, the Examiner restricts and withdraws newly submitted claims 42-53 and 54-65 as each being independent and distinct from the invention originally claimed; characterizes the declaration filed June 26, 2007, under 37 CFR 1.132, insufficient to overcome the rejection of claims 22-25, 27-30 and 33-35 under 35 USC §

102(e) based on Ash, et al (U.S. Patent No. 5,947,953); rejects claims 22-25, 27-30, 33 and 34 under 35 USC § 102(a) as anticipated by Ash, et al (U.S. Patent No. 5,947,953); rejects claim 35 under 35 USC §103(a) as unpatentable over Ash, et al (U.S. Patent No. 5,947,953); and rejects claims 31 and 32 under 35 USC §103(a) as unpatentable over Ash, et al (U.S. Patent No. 5,947,953) in view of Melsky, et al (U.S. Patent No. 5,704,15).

Restriction

The Examiner restricts and withdraws newly submitted claims 42-53 and 54-65, characterizing each as independent and distinct from the invention originally claimed. The Examiner characterizes each set of claims as including steps not recited in the methods of previously examined independent claims 22 and 35.

In view of the Examiner's restriction, Applicant cancels claims 42-53 and 54-65. Applicant makes no representation by the claim cancellation regarding the merits of the restriction, and/or the possible existence of multiple independent and/or distinct inventions among the claims of record. Applicant reserves the right to pursue the subject matter of the non-elected claims in one or more related applications. Applicant asserts that there is no change of inventorship as a result of the claim cancellation.

Claim Rejections – 35 USC § 102

The Examiner rejects claims 22-25, 27-30, 33 and 34 under 35 USC § 102(a) as anticipated by Ash, et al (U.S. Patent No. 5,947,953). Further, the Examiner characterizes the declaration filed June 26, 2007, under 37 CFR 1.132, insufficient to overcome the prior rejection of claims 22-25, 27-30 and 33-35 under 35 USC § 102(e) based on Ash, et al (U.S. Patent No. 5,947,953).

Applicants respectfully traverse the claim rejections under 35 USC § 102(a), and disagree that the declaration filed June 26, 2007, under 37 CFR 1.132, is insufficient to overcome the prior rejection of claims 22-25, 27-30 and 33-35 under 35 USC § 102(e) based on Ash. Applicants contend that United States Patent No. 5,947,953 to Ash, et al., is not prior art against the claimed invention, as the pertinent subject matter disclosed but not claimed in Ash and relied upon by the Examiner in the prior § 102(e) rejection is not invention “by another.”

Nonetheless, Applicants amend independent claim 22, and dependent claims 27, 29 and 32, directing the claims to further features of the invention. Ash (US 5,947,953) does not disclose each and every element of the claimed invention.

Regarding independent claims 22 and 35, as amended, Ash does not disclose, teach or suggest bonding exterior surfaces of the first and the second distal end tubes, after splitting a unitary catheter tube longitudinally to form the first and the second distal end tubes, to releasably attach the first and the second distal end tubes. Additionally, Ash does not teach a unitary catheter tube with an outer wall having a smooth, curved and generally convex surface without ridges or grooves. In Ash, the outer wall of the catheter assembly 10 includes ridges or grooves, due to membrane 46 having a cross-sectional length t_m being a fraction of the outer diameter OD_1 of catheter assembly 10. In Ash, the “cross-sectional length t_m also defines the distance between the generally flat side surfaces 38, 44. *See Ash, col. 6, lines 54-58, and Figures 1, 1a, and 4A-4E, particularly 4A.*

In view of the above, Applicants respectfully request that the Examiner withdraw the rejections of claims 22-25, 27-30, 33 and 34 under 35 USC § 102(a) as anticipated by Ash (U.S. Patent No. 5,947,953).

Claim Rejections – 35 USC § 103

The Examiner rejects claim 35 under 35 USC §103(a) as unpatentable over Ash, et al (U.S. Patent No. 5,947,953); and rejects claims 31 and 32 under 35 USC §103(a) as unpatentable over Ash, et al (U.S. Patent No. 5,947,953) in view of Melsky, et al (U.S. Patent No. 5,704,15). Applicants respectfully traverse the claim rejections under 35 USC §103(a), and submit that a prima facie case of obviousness has not been established.

Regarding the §103 rejection of claim 35 over Ash, alone, the Examiner states that Ash does not teach releasably re-attaching the first and second distal end tubes; however, since Ash teaches a configuration where the distal end tubes are separated and a configuration where the distal end tubes are attached, it would be obvious to modify the method of Ash to include the step of re-attaching the first and second distal end tubes, with a reasonable expectation of success, to allow easier removal of the catheter assembly from a surgical site.

Applicants disagree, as Ash alone does not teach all of the claimed features, does not provide the requisite expectation of success, and is not modifiable, as suggested by the Examiner, to accomplish the intended function. Indeed, Ash, alone, teaches away from the claimed invention.

First, as detailed above, Ash does not teach a unitary catheter tube with an outer wall having a smooth, curved and generally convex surface without ridges or grooves, as featured in claim 35, as amended. Accordingly, Ash does not teach or suggest all of the features of claim 35.

Second, the separation distance between the generally flat side surfaces 38, 44, of the catheter assembly 10 of Ash, defined by the cross-sectional length t_m , would preclude, in the

teaching of Ash, the requisite expectation of success necessary to re-attach the first and second distal end tubes after tearing/splitting the frangible membrane 46. Indeed, the re-attachment of the generally flat side surfaces 38, 44, would require a surface bonding of two distal end tubes previously separated by a distance t_m , where the respective lumens would still be separated by a distance t_m over the unitary catheter portion of the assembly 10.

Accordingly, the transition point, in the Examiner's proposed embodiment, of the unitary catheter tube to the two separate distal end tubes, would be hampered by, and would somehow have to compensate for, a conflicting separation distance t_m on the unitary catheter tube side of the transition point. The conflicting separation distance t_m , in the Examiner's proposed embodiment, would hamper insertion of the catheter assembly, and create a means for leakage. A method and design to compensate for the conflicting separation distance t_m at the transition point is undefined in the teaching of Ash. Therefore, Ash is not modifiable, as suggested by the Examiner, to accomplish the intended function. Ash also does not provide a reasonable expectation of success; but rather teaches away from the claimed invention.

Lastly, and alternatively, the present invention solves a long felt need, and provides advantages not disclosed in the prior art. The present invention assists the prevention of leakage at the site of vessel entry through use of an exterior of the unitary catheter 12 that includes a smooth, curved, and generally convex surface without ridges or grooves. See paragraphs [0014] and [0054] of the present specification.

A vessel wall can easily seal around the smooth, generally convex exterior surface, without ridges or grooves, of the present invention. However, if round, individual distal end tubes 14, 16 are located at the insertion site, the vessel wall will not seal as easily, or will not be

capable of sealing as tightly, as if a single, rounded, generally oval or circular unitary catheter 12 type configuration is used, as a potential risk of leakage exists around and between multiple, rounded distal end tubes due to their "figure-8" configuration. See paragraph [0085] of the present specification. Ash is an example of a "figure-8" configuration. See Ash, Figures 4A-4E. Independent claims 22 and 35, as amended, and added independent claim 88, clarify and particularly point out these advantages of the present invention.

Regarding the rejection of claims 31 and 32 under 35 USC §103(a) as unpatentable over Ash, et al (U.S. Patent No. 5,947,953) in view of Melsky, et al (U.S. Patent No. 5,704,915), Applicants also respectfully traverse the claim rejections under 35 USC §103(a), submitting that a prima facie case of obviousness has not been established. For all of the reasons detailed above, Ash in view of Melsky does not teach all of the claimed features of dependent claims 31 and 32, does not provide the requisite expectation of success, and is not modifiable, as suggested by the Examiner, to accomplish the intended function. Claims 31 and 32 are dependent on independent claim 22.

In view of the above, Applicants respectfully request that the Examiner withdraw the rejections of claim 35 under 35 USC §103(a) as unpatentable over Ash, and claims 31 and 32 under 35 USC §103(a) as unpatentable over Ash in view of Melsky.

Claims Added by this Response and Amendment

Claims 66-101 are added in this Response and Amendment to more completely cover certain aspects of Applicants' invention. The recitations of claims 66-101 are patentable over the prior art of record for the reasons detailed above, as the added claims include features similar to

those currently and variously presented. Additionally, for these reasons the added claims are fully supported throughout the specification and the drawings.

Nonetheless, by way of example, and for the convenience of the Examiner, disclosure for recited features can be found in the specification at least as follows:

- Features added to independent claims 1 and 35, and included in new independent claim 88: paragraphs [0014] and [0054];
- Features of new claims 67-69, 76-81 and 94-96: paragraphs [0087] and [0088];
- Features of new claims 73, 85 and 100: paragraph [0052];
- Features of new claims 72, 84 and 99: paragraph [0102]; and
- Features of new claims 75, 87 and 101: paragraph [0104].

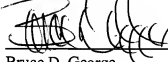
CONCLUSION

In light of the above amendments and remarks, Applicants submit that pending claims 22-27, 29-35 and 66-101 are allowable, that the application is in condition for allowance, and requests that the Examiner issue an early notice of allowance. The Examiner is invited to call the undersigned attorney to advance prosecution of this application.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment of the fees associated with this communication to Deposit Account No. 02-2555.

Date: August 15, 2008

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bruce D. George", is written over a horizontal line.

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